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10/552,094	10/04/2005	Richard R. Navarro	ZP193-05002	4200

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EXAMINER	
HARVEY, JULIANNA NANCY	
ART UNIT	PAPER NUMBER
3733	
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10/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,094	NAVARRO ET AL.	
	Examiner	Art Unit	
	Julianna N. Harvey	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-47,112 and 115-135* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-47,112 and 115-135* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 July 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *18 July 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

In light of Applicant's amendments to the drawings and specification, the objection to the drawings, as stated in the Office Action mailed on 7 January 2008, have been withdrawn.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "38" has been used to designate both a concavity, a force transducer, a strain gauge, and a load or pressure sensor. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "38a", "38b", "38c", "41", and "43" (all in Fig. 22). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are

required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

In light of Applicant's amendments to some claims and cancellation of others, the objections to claims 2, 54, 72, 82, 87, 90, 91, 100, 104-107, 109, and 111-114, as stated in the Office Action mailed on 7 January 2008, have been withdrawn.

Claim 117 is objected to because of the following informalities: "distal of said first projection" should be "distal **end** of said first projection" (line 2). Appropriate correction is required.

Claim Rejections - 35 USC § 112

In light of Applicant's amendments to some claims and cancellation of others, the rejection of claims 22, 42, 64, and 92 under 35 USC § 112 first paragraph, as stated in the Office Action mailed on 7 January 2008, has been withdrawn.

In light of Applicant's amendments to some claims and cancellation of others, the rejection of claims 5, 12, 14, 20, 21, 27, 40, 41, 46, 49, 50, 52, 54, 56, 62, 63, 69, 78, 82, 84, 87, 90, 91, 97, 103-105, 108, 109, and 114 under 35 USC § 112 second paragraph, as stated in the Office Action mailed on 7 January 2008, has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32, 34, 38, 112, 115-119, 122, and 132-135 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrington (US 5,893,889 A).

Regarding **claim 32**, Harrington discloses an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate ("34") having an upper surface ("40") and a lower surface ("44"); a first projection (frustoconical projection) extending from the lower surface of the first endplate terminating in a first distal end (flat surface of frustoconical projection); a second endplate ("32") having an upper surface ("58") and a lower surface ("36"); a second projection (frustoconical projection) extending from the upper surface of the second endplate and substantially aligned with the first projection, the second projection terminating at a second distal end (flat surface of frustoconical projection) to form a gap

having a predetermined distance between the first distal end and the second distal end; and a visco-elastic cushion ("68") interposed between the first and second endplates further comprising a cavity for receiving the first and second projections; wherein *contact between the first distal end of the first projection and the second distal end of the second projection limits the first endplate and the second endplate from moving relatively closer to one another* (Fig. 2). Regarding **claim 34**, Harrington discloses that the first projection (frustoconical projection extending from "44") of the first endplate ("34") is substantially cylindrically shaped (Fig. 2). Regarding **claim 38**, Harrington discloses that the upper surface ("40") of the first endplate ("34") and the lower surface ("36") of the second endplate ("32") further comprise appurtenances ("38" and "42") *that aid in securing the prosthesis to adjacent vertebrae* (Fig. 2). Regarding **claim 115**, Harrington discloses that the first distal end (flat surface of frustoconical projection) of the first projection (frustoconical projection extending from "44") and the second distal end (flat surface of frustoconical projection) of the second projection (frustoconical projection extending from "58") are substantially planar (Fig. 2). Regarding **claim 116**, Harrington discloses that *contact between the first distal end of the first projection and the second distal end of the second projection permits at least some motion in a direction perpendicular to a direction that brings the first endplate and the second endplate closer to each other.*

Regarding **claim 112**, Harrington discloses an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate ("32") having an upper surface ("36") and a lower surface ("58"); a first projection

(frustoconical projection) extending from the lower surface of the first endplate terminating in a first distal end (flat lower surface of frustoconical projection); a second endplate ("34") having an upper surface ("44") and a lower surface ("40"); a second projection (frustoconical projection) extending from the upper surface of the second endplate and substantially aligned with the first projection, the second projection terminating at a second distal end (flat upper surface of frustoconical projection) to form a gap having a predetermined distance between the first distal end and the second distal end; and a polymeric cushion ("68") interposed between the first and second endplates further comprising a cavity for receiving the first and second projections; wherein *contact between the first distal end of the first projection and the second distal end of the second projection limits the first endplate and the second endplate from moving relatively closer to one another* (Fig. 2). Regarding **claim 117**, Harrington discloses that the first distal (flat lower surface of frustoconical projection) end of the first projection (frustoconical projection extending from "58") and the second distal end (flat upper surface of frustoconical projection) of the second projection (frustoconical projection extending from "44") are substantially planar (Fig. 2). Regarding **claim 118**, Harrington discloses that *contact between the first distal end of the first projection and the second distal end of the second projection permits at least some motion in a direction perpendicular to a direction that brings the first endplate and the second endplate closer to each other.*

Regarding **claim 119**, Harrington discloses an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate

("34") having an upper surface ("40") and a lower surface ("44"); a second endplate ("32") having an upper surface ("58") and a lower surface ("36"); a projection (frustoconical projection) extending from the upper surface of the second endplate toward the first endplate, the projection terminating at a distal end (flat surface of frustoconical projection) to form a gap having a predetermined distance between the distal end and the first endplate; and a visco-elastic cushion ("68") interposed between the first and second endplates having a cavity for receiving the projection; wherein the distal end of the projection is substantially planar (Fig. 2). Regarding **claim 122**, Harrington discloses that the upper surface ("40") of the first endplate ("34") and the lower surface ("36") of the second endplate ("32") further comprise appurtenances ("38" and "42") *that aid in securing the prosthesis to adjacent vertebrae* (Fig. 2). Regarding **claim 132**, Harrington discloses that *contact between the projection and the first endplate stops compressive motion but allows at least some amount of shear motion*.

Regarding **claim 133**, Harrington discloses an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate ("32") having an upper surface ("36") and a lower surface ("58"); a second endplate ("34") having an upper surface ("44") and a lower surface ("40"); a projection (frustoconical projection) extending from the upper surface of the second endplate toward the first endplate, the projection terminating at a distal end (flat upper surface of frustoconical projection) to form a gap having a predetermined distance between the distal end and the first endplate; and a polymeric cushion ("68") interposed between the

first and second endplates having a cavity for receiving the projection; wherein the distal end of the projection is substantially planar (Fig. 2).

Regarding **claim 134**, Harrington discloses an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate ("32") having an upper surface ("36") and a lower surface ("58"); a second endplate ("34") having an upper surface ("44") and a lower surface ("40"); a projection (frustoconical projection) extending from the upper surface of the second endplate toward the first endplate, the projection terminating at a distal end (flat upper surface of frustoconical projection) to form a gap having a predetermined distance between the distal end and the first endplate; and visco-elastic cushion ("68") interposed between the first and second endplates having a cavity for receiving the projection; wherein *contact between the distal end of the projection and the first endplate permits at least some motion in a direction perpendicular to a direction that brings the first endplate and the second endplate closer to each other* (Fig. 2).

Regarding **claim 135**, Harrington discloses an artificial intervertebral disc prosthesis having an anterior portion and a posterior portion, comprising: a first endplate ("32") having an upper surface ("36") and a lower surface ("58"); a second endplate ("34") having an upper surface ("44") and a lower surface ("40"); a projection (frustoconical projection) extending from the upper surface of the second endplate toward the first endplate, the projection terminating at a distal end (flat upper surface of frustoconical projection) to form a gap having a predetermined distance between the distal end and the first endplate; and a polymeric cushion ("68") interposed between the

first and second endplates having a cavity for receiving the projection; wherein *contact between the distal end of the projection and the first endplate permits at least some motion in a direction perpendicular to a direction that brings the first endplate and the second endplate closer to each other* (Fig. 2).

The text italicized above corresponds to statements of intended use or other functional statements. These statements do not impose any structural limitations on the claims distinguishable over Harrington, which is capable of being used as claimed if one so desires. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). In addition, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33, 35-37, 120, and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889 A).

Harrington fails to disclose that the first projection of the first endplate extends a distance of approximately 1 to approximately 3 millimeters from the lower surface of the first endplate (**claim 33**), that the first distal end has a radius of approximately 2 millimeters to approximately 15 millimeters (**claim 35**), that the second projection of the second endplate extends a distance of approximately 3 millimeters to approximately 6 millimeters from the upper surface of the second endplate to the second distal end (**claim 36**), and that the gap between the first distal end and the second distal end is approximately 1 millimeters to approximately 2 millimeters (**claim 37**). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Harrington such that the first projection of the first endplate extends a distance of approximately 1 to approximately 3 millimeters from the lower surface of the first endplate (**claim 33**), that the first distal end has a radius of approximately 2 millimeters to approximately 15 millimeters (**claim 35**), that the second projection of the second endplate extends a distance of approximately 3 millimeters to approximately 6 millimeters from the upper surface of the second endplate to the second distal end (**claim 36**), and that the gap between the first distal end and the second distal end is approximately 1 millimeters to approximately 2 millimeters (**claim 37**), since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Harrington fails to disclose that the projection of the second endplate extends a distance of approximately 3 millimeters to approximately 6 millimeters from the upper surface of the second endplate to the distal end (**claim 120**) and that the gap between the distal end and the first endplate is approximately 1 millimeters to approximately 2 millimeters (**claim 121**). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Harrington such that the projection of the second endplate extends a distance of approximately 3 millimeters to approximately 6 millimeters from the upper surface of the second endplate to the distal end (**claim 120**) and that the gap between the distal end and the first endplate is approximately 1 millimeters to approximately 2 millimeters (**claim 121**), since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 39 and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889 A) as applied to claims 32 and 119 above, and further in view of Ishikawa et al. (US 6,447,448 B1). Harrington discloses the claimed invention except a force or pressure transducer located within the prosthesis for allowing the measurement and transmittal of information about loads experienced by the prosthesis. Ishikawa et al. teach an intervertebral disc containing a ball sensor ("808" in Fig. 8) which is similar to the ball IC (column 9, lines 56-57) that contains a force transducer ("160" in "110" in Fig. 4A). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device disclosed by Harrington with a force transducer as suggested by Ishikawa et al. as doing so provides means to monitor

stress and compression forces to assure proper alignment of the vertebrae and the development of forces due to vertebral degeneration and disc malfunction (column 9, lines 54-61 of US 6,447,448 B1).

Claims 40, 41, 124, and 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889 A) in view of Ishikawa et al. (US 6,447,448 B1) as applied to claims 39 and 123 above, and further in view of Kovacevic (US 5,197,488 A). Harrington and Ishikawa et al. teach the claimed invention except that the second projection houses at least a portion of a package of signal conditioning and amplification electronics connected to the transducer within the second projection and at other peripheral locations around the second endplate (**claims 40 and 124**) and that the second projection houses electronics connected to the transducer within the second projection and at other peripheral locations around the second endplate (**claims 41 and 125**). Ishikawa et al. teach that the ball IC contains a processor ("140" in Fig. 4A) which digitizes (i.e., conditions) the sensor data (column 7, lines 34-35) and a transmitter ("150" in Figs. 4A and 4B) that contains an amplifier ("458" in Fig. 4B). Kovacevic teaches a device where the transducer is located on a plate positioned between the two endplates ("14" positioned between "13" and "16" in Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Harrington with a processor and an amplifier (**claims 40 and 124**), as suggested by Ishikawa et al., as the processor digitizes the data to make it compatible with external data reception devices and the amplifier strengthens the data signal prior to signal output. It would have been further obvious to place such a package (the transducer, the

processor, and the amplifier) within the second projection (**claims 40, 41, 124, and 125**) as doing so would protect the processor and amplifier from potential compression against the visco-elastic cushion ("68" in Fig. 2 of US 5,893,889) and allow the transducer to measure the pressure on the endplate without interference from the visco-elastic cushion. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place a transducer between the endplates (**claims 40, 41, 124, and 125**), as suggested by Kovacevic, as this would allow the measurement of the pressure on the visco-elastic cushion ("68" in Fig. 2 of US 5,893,889). It would have been further obvious to place this transducer on the surface of the second endplate (**claims 40, 41, 124, and 125**) as it would still be in contact with the visco-elastic cushion and could easily be connected to the amplifier and processor located within the second projection, eliminating the need to include another amplifier and processor that could potentially be damaged from compression between the visco-elastic cushion and the second endplate.

Claims 42 and 126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889 A) in view of Ishikawa et al. (US 6,447,448 B1) as applied to claims 39 and 123 above, and further in view of Wanderman et al. (US 5,511,561) and Medical Electronics Manufacturing (hereinafter referred to as "MEM"; Dorren, Sonny, *Designing Compact Medical Devices with Flex Circuitry*). Harrington and Ishikawa et al. teach the claimed invention except that the second endplate comprises a flex circuit that includes a load sensor embedded onto the upper surface of the second endplate. Wanderman et al. teach a flex circuit that includes a load sensor

(column 5, lines 8-11). MEM teaches that flex circuits can be used in implanted medical devices (last sentence of third paragraph). It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Harrington with a flex circuit that includes a load sensor, as suggested by Wanderman et al. and MEM, as flex circuits reduce the size of the package of electronics and have lower assembly costs. It would have been further obvious to embed the flex circuit onto the surface of one of the endplates as that would allow the sensor to measure the load on the visco-elastic cushion. As such, embedding the flex circuit onto the surface of the second endplate is obvious as it is just a matter of individual preference whether the circuit is located on the surface of the first or second endplate as both locations would provide the same data.

Claims 43, 46, 47, 127, 130, and 131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889 A) in view of Steffee (US 5,071,437 A). Harrington discloses the claimed invention except that the first and second endplates comprise a biocompatible material (**claims 43 and 127**), that the posterior portion of each of the first and second endplates comprises a concavity that defines posterior lobes projecting from the posterior portions of each of the first and second endplates (**claims 46 and 130**), and that each of the first and second endplates have an external surface therearound defining a generally "D" shape (**claims 47 and 131**). Steffee teaches an intervertebral disc prosthesis where the endplates are biocompatible (column 4, lines 43-53). Steffee also teaches that the intervertebral disc prosthesis comprises first and second endplates, both with a concave portion and posterior lobes

(column 4, lines 26-29; Figs. 2 and 3) such that the external surfaces of the endplates ("12" and "14" in Fig. 2) create a "D" shape (Figs. 2 and 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Harrington prosthesis such that the endplates are made of a biocompatible material (**claims 43 and 127**), as suggested by Steffee, as the body is less likely to have an adverse reaction to biocompatible implants. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Harrington prosthesis such that the posterior portion of each endplate comprises a concave portion and posterior lobes (**claims 46 and 130**), as disclosed by Steffee, resulting in "D"-shaped endplates (**claims 47 and 131**) as this configuration resembles that of a natural disc (column 4, lines 26-32 of US 5,071,437).

Claims 44 and 128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889 A) in view of Steffee (US 5,071,437 A) as applied to claims 43 and 127 above, and further in view of Cauthen (US 6,179,874 B1). Harrington and Steffee teach the claimed invention except that the endplates are made from stainless steel, stainless steel alloys, titanium, titanium alloys, cobalt chromium molybdenum (hereinafter referred to as "CoCrMo") alloys, or composite materials. Steffee teaches that the endplates can be made of 316 LVM stainless steel (a stainless steel alloy), titanium, a titanium alloy, or a CoCrMo alloy (column 4, lines 43-53). Cauthen teaches that the endplates can be made of zirconium oxide ceramic (a composite material) or stainless steel (column 5, lines 23-28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the

endplates of the Harrington device from stainless steel, a stainless steel alloy, titanium, a titanium alloy, a CoCrMo alloy, or a composite material as suggested by Steffee and Cauthen because these materials are high-strength and biocompatible.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889 A) in view of Steffee (US 5,071,437 A) and Cauthen (US 6,179,874 B1) as applied to claim 44 above, and further in view of Kenna (US 4,714,469 A) and Wang et al. (US 4,714,468 A). Harrington, Steffee, and Cauthen teach the claimed invention except that the endplates are made from an alloy containing approximately 66% cobalt, approximately 28% chromium, and approximately 6% molybdenum. Kenna teaches an intervertebral disc device where the rigid body is made of Vitallium (column 3, lines 59-63). Wang et al. teach that a typical Vitallium composition is 64.8% cobalt, 28% chromium, and 5.5% molybdenum (column 1, lines 28-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the endplates of the Harrington device from Vitallium, as suggested by Kenna, as Vitallium has high corrosion resistance (column 1, lines 28-30 of US 4,714,468).

Claim 129 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889 A) in view of Steffee (US 5,071,437 A) as applied to claim 127 above, and further in view of Kenna (US 4,714,469 A) and Wang et al. (US 4,714,468 A). Harrington and Steffee teach the claimed invention except that the endplates are made from an alloy containing approximately 66% cobalt, approximately 28% chromium, and approximately 6% molybdenum. Kenna teaches an intervertebral

disc device where the rigid body is made of Vitallium (column 3, lines 59-63). Wang et al. teach that a typical Vitallium composition is 64.8% cobalt, 28% chromium, and 5.5% molybdenum (column 1, lines 28-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the endplates of the Harrington device from Vitallium, as suggested by Kenna, as Vitallium has high corrosion resistance (column 1, lines 28-30 of US 4,714,468).

Response to Arguments

Applicant's arguments filed 7 July 2008 have been fully considered but they are not persuasive. Applicant argues that the frustoconical surfaces of Harrington never contact each other to limit motion between two endplates. The examiner respectfully disagrees. First of all, the claims do not state that the surfaces must directly contact each other, and thus indirect contact through an intermediate member would be permissible. Furthermore, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). As such, if one so desired, one could foreseeably compress the Harrington prosthesis sufficiently to create direct contact between the frustoconical surfaces.

The remainder of Applicant's arguments with respect to claims 32 and 112 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. N. H./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733